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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,346

11/29/2001

Karl Engelhard

P01,0310

6064

26574

7590

04/27/2004

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT

PAPER NUMBER

3737

2

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,346

Applicant(s)

ENGELHARD ET AL.

Examiner

Eleni Mantis Mercader

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al.'800 in view of Tso et al.'929.

Atalar et al.'800 teach a minimally invasive treatment of a prostate tumor including conducting a magnetic resonance-guided biopsy to obtain a biopsy sample from a region of the prostate in which prostate pathology is identified in order to diagnose and if necessary direct further therapy of interest (see col. 8, lines 35-67 and also see col. 2, lines 34-59). Furthermore, Atalar et al.'800 teach injecting a local cancer therapeutic agent and/or contrast agent into the region of interest with magnetic resonance guidance (see col. 12, lines 13-25).

Atalar et al.'800 do not explicitly teach a follow-up examination of the patient to determine whether a change in the prostate pathology has occurred at a later time and prescribing further treatment for said patient dependent on said follow-up examination.

In the same field of endeavor, Tso et al.'929 teach use of MRI imaging post therapy at a later time in order to determine the treatment efficacy (see paragraph 0109).

It would have been obvious to one skilled in the art at the time that the invention was made to have utilized a follow-up examination at a later time with MRI imaging in the invention of Atalar et al.'800 as that would be done as a way to determine the efficacy of treatment (as

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taught by Tso et al.'929) and as is also well known to skilled artisans in order to determine whether additional treatment is needed and which therapeutic treatment is more appropriate.

Furthermore, Tso et al.'929 teach the use of PSA prior to therapy and post-therapy as a secondary indication of treatment efficacy (see paragraph 0109). The PSA value of greater than 5 is well known to those skilled in the art as the determining factor for prostate cancer diagnosis.

Finally Atalar et al.'800 teach radiotherapy or surgical excision as a way of treating the cancerous region (see col. 8, lines 35-67). The timing of such treatment whether right after biopsy or at a later time is dependant on the diagnostic determinations of the physician and patient choice as this is well within the knowledge of skilled artisans.

The use of an anesthetic is well known to skilled artisans for any procedure, which may bring discomfort to the patient.

3. Claims 6-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al.'800 in view of Tso et al.'929 as applied to claim 1 above, and further in view of Diamandis et al.'118.

Atalar et al.'800 in view of Tso et al.'929 teach all the features of the current invention except for the specific use of toxin, ethanol or ethanol type combinations, a cytostatic therapeutic agent, a contrast agent such as gadolinium, and hormones.

In the same field of endeavor, Diamandis et al.'118 recognizes that these agents have been used in the prostate and extends these to other types of cancer (see col. 1, lines 11-15). Diamandis et al.'118 teach the specific use of toxin (see col. 4, lines 17-22), ethanol or ethanol type combinations (see col. 11, lines 50-57), a cytostatic therapeutic agent (see claim 10), a

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contrast agent such as gadolinium (see col. 3, lines 26-30), and hormones (see col. 7, lines 13-42).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Atalar et al.'800 in view of Tso et al.'929 and used the specific agents as taught by Diamandis et al.'118 in order to diagnose and treat the area of interest such as the prostate.

### *Conclusion*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Uzgiris et al.'204 teach an intracavity probe for MR image guided biopsy.


Mikus et al.'170 teach a computer guided surgery for prostatic nerve sparing.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM